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Usability evaluation of an adaptation of the WHO classification for patient safety

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Abstract: Background. The Danish National Board of Health is implementing the International Classificatin for Patient Safety (ICPS) in the national reporting system (ICPS-DK). **Study objective**. Test the usability of ICPS-DK consisting of 29 non-exclusive categories and to incorporate amendments to the system before final launch. The present paper aims to disseminate results about usability aspects of the ICPS. **Design.** Data about usability aspects collected via questionnaire and written comments from a reliability test. **Setting.** Sixty-five risk managers made optional written comments while classifying 58 selected reports, of which 56 participants subsequently completed a questionnaire about the usability of ICPS-DK and problems with specific incident types. **Participants.** Thirty-three respondents from units with experience with the previous reporting system, and 32 respondents representing new users outside the hospitals. **Main outcome measure(s).** Ease of use, identification of problematic incident types, and verbal specification of problems. **Results**. Participants were neutral (46 %) or found it (fairly) easy to use (49 %). Difficulties with distinguishing *Administrative Processes* from *Clinical Processes*, and some problems with individual subtypes. *Communication and Documentation* and *Resources and Organisation* perceived as very broad and needing specification. Some participants concerned about non-exclusive categories leading to excessive use of types for individual reports. **Conclusions.** Although ICPS-DK is comprehensive, few respondents found it difficult to use. The authors recommend a simple adaptation of ICPS with incident types, which may be expanded to include systemic factors. Excessive use of certain types reducible by specification and avoiding speculation about causes not explicitly contained in incident report.

Keywords: Incident reporting, Patient safety, Taxonomy, Organizational factors

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1 INTRODUCTION

The Danish national reporting system for patient safety events, which was the first nationwide, mandatory and non-punitive reporting system in healthcare, was launched in January 2004 to support learning from the reporting of adverse events occurring in the hospital sector. Since its introduction, the number of reports has grown every year, from 5,000 in 2004 to 34,000 in 2010 [1]. Adverse events in the first version were classified into nine incident types.

With the introduction of a more comprehensive reporting system (introduced September 2010) the National Board of Health decided to adapt the WHO International Classification for Patient Safety (ICPS) [2-5] for the classification of incident types. The Danish adaptation of ICPS (hence forth referred to as ICPS-DK) was intended to be as close to the original ICPS as to allow international comparison while at the same time be more manageable and time efficient in the everyday classification of incidents. Reporting of incidents to the new system has been extended to include general practitioners, municipal healthcare (home care, nursing homes), dentistry and other specialist clinics; and later, patients and their relatives [6]. Incidents are first reported by a healthcare person often directly involved submitting a written description, and these reports are later to be classified by another person more familiar with patient safety issues, e.g. a risk manager in a hospital.

It was decided by the National Board of Health that the ICPS-DK should be divided into a core of incident types into which all incidents must be classified (the mandatory part) and a more extensive part (the optional part) intended for reports that describe serious incidents, which typically contain greater descriptive specification, and/or events where the learning potential is particularly large.

2 OBJECTIVE

This paper aims to describe the Danish adaptation of the ICPS, report the results of a usability test of that adaptation and discuss the possible implications for the further development of the ICPS. At the same time, a parallel paper reports on results of a reliability test of the mandatory part of ICPS-DK [7]. The present paper focuses mainly on issues that have relevance for the general application of the ICPS, rather than those issues that are specific to the Danish context and implementation.

Readers considering implementation of ICPS in other countries may be interested in learning from the Danish experience with a selective adaptation. The ICPS in total is extensive, and others will probably consider some form of selective adaptation in order to facilitate a reporting process with a reasonable use of resources, while providing useful information for further analysis. ICPS-DK represents some suggestions for a partial implementation, while the usability study explores problems and advantages with that adaptation. Some of the most significant elements of the adaptation are presented in the next section, but can be summarized as: no separate classification of contributing factors, no separate indication of *problems*, and only indication of *processes* for a few incident types, and the expansion of the incident type 'Documentation' to include communication.

3 ADAPTATION OF THE ICPS

The World Health Organization's World Alliance has developed the ICPS in order to establish "a common format to facilitate aggregation, analysis and learning across disciplines, borders and time" [8]. While the ICPS consists of ten high level classes, including *Incident Type, Patient Outcomes, Detection* and *Contributing Factors/Hazards*, ICPS-DK is based on only one of these [2;4], viz. *Incident types*.

In the mandatory ICPS-DK it is sufficient to use the incident type for most of the 13 types, since this information will be adequate for a minimal classification. Four incident types require further specification by the user (see Table 1). When classifying an incident into *1.Administrative processes* or *2.Clinical processes* a user is thus required to further indicate the relevant specific type of process where the problem occurred, e.g. a *Handover…* or *Diagnosis*. This specification should make it possible to distinguish *1.Administrative processes* from other incident types such as *2.Clinical processes* and *12.Resources and organization.* Similarly, *2.Clinical processes* requires a more detailed classification by indicating specific processes, since it encompasses the majority of critical healthcare processes and would otherwise be too broad to provide meaningful information. Two other incident types, *9.Self-harm…* and *10.Patient accident*, also require specification by subtypes.

ICPS-DK has not implemented the separate class for *Contributing factors* from the original ICPS and does therefore not offer a separate class for indication of causes. Instead, some incident types can be used to include indicate factors, e.g. organizational factors may be indicated by incident type *Resources and Organization*, and one human factor – communication – is covered by the modified incident type *Healthcare communication and documentation*. This use has required some modification of the original ICPS types by expanding them to include circumstances or conditions that "can not be incidents in their own right" [2]. In particular, *Resources and organization* in ICPS is intended for only occasional failures such as a short and non-recurring staff shortage, power failure, etc., while the corresponding type in ICPS-DK has been defined to include also so-called systemic causes [9] or latent conditions such as recurring staff shortages, poor maintenance of equipment, poor or lacking procedure etc. [10].

The ICPS type for problems *Documentation* has also been expanded significantly in ICPS-DK to include a broader set of incidents that involve, e.g., misunderstandings or communication failures between health care

providers. The expanded type *Healthcare communication and documentation* thus includes *communication* problems that are often treated as 'contributing factors', e.g. as human (*Staff* and *Patient*) factors in ICPS, and it can now be used to indicate factors in a broad range of incidents. With this definition, documentation is treated as a means of communication, and documentation problems are treated as a subclass of a much broader category of communication problems.

Table 1. Incident types and subtypes with number of comments during the test.

INCIDENT TYPE	COMMENTS
1. Administrative processes	**44**
Handovers/ shift changes/sector changes/ Referral	12
Appointment	
Waiting list/ waiting time/ continuity gap	22
Admissions/reception	3
Discharge	
Patient identification	
Informed consent	
Other/not known	
2. Clinical processes	**28**
Screening/Prevention/Routine Checkup	8
Diagnosis/examination/assessment	4
Treatment/intervention/monitoring	4
Care/rehabilitation	3
Test/survey/test results	4
Detention/fixation	4
Other/not known	
3. Professional communication and documentation	**14**
4. Medication	**6**
5. Medical equipment	**3**
6. Infection	**2**
7. Blood and blood components	**0**
8. Gases and air for medical use	**0**
9. Self-harm, suicide attempts or suicide	**5**
Self-harm	
Suicide attempt	
Suicide	
10. Patient accident	**1**
Fall	
Other	
11. Buildings and infrastructure	**3**
12. Resources and organisation	**16**
13. Other incident type	

Classification based on ICPS-DK is non-exclusive in the sense that one case may involve more than one incident type, whether because a report describes several incidents, or to describe causes implied in the report. ICPS-DK is thus non-exclusive both in accordance with the definitions in ICPS and to allow an indication of causes without a separate structure for 'contributing factors', and at this point it differs from the previous reporting system, which required classification into only one of seven exclusive categories. Yet,

classification should be limited to the text submitted by the reporter, without indicating incident types based on speculation beyond the description, e.g. about possible organizational causes.

4 METHODS AND MATERIALS

The pilot test of the ICPS-DK consisted of a reliability test and a questionnaire. The usability test described in this paper comprises users' written comments made during the reliability test and the results from the questionnaire survey.

Fifty-eight test cases were selected to ensure that each of the 29 incident types would be represented by two cases. The logic of non-exclusive categorization implies that several of the cases might also involve one or more additional incident types. A user guide instructed raters to use as many different incident types and subtypes as warranted by the case description and to avoid speculation beyond what is stated in the target report.

A total of 91 participants were selected from the various professional groups that will be using the reporting system in the future. Forty-three participants were invited from the somatic disciplines at the hospitals, which were already familiar with the previous version of the reporting system. Twenty-six were invited from other hospital groups not previously included in the reporting system: psychiatry, ambulance and therapists. Outside the hospital sector 17 were invited from the municipalities responsible for nursing homes and other facilities, and 5 general practitioners.

A list of the 29 types and subtypes (the taxonomy comprising the mandatory part) with a user guide and test cases were sent to participants in March 2010, with ten days to respond. Participants were invited to write comments when classifying a case. After two reminder e-mails to non-responders, 65 raters returned their responses (response rate = 71%).

After completion of the pilot test, respondents received an electronic questionnaire asking them to: 1) rate the ease or difficulty of using the classification; 2) rate their own prior experience with classifying incidents, 3) indicate particularly difficult incident types; 4) describe problems with incomprehensibility or lack of clarity in the classification. The first three were Likert-style items, the last an open textual response item. Responses were received from 56 of the 65 raters (response rate = 86%).

5 RESULTS

50 % of respondents had much experience with classifying incidents, 16 % had some experience, while 34 % had no experience. In general, participants were neutral or moderately positive about the ease of using the classification, while only 5 % found it difficult to use (Table 2).

Table 2. How easy or difficult is it to use the classification?

N=56	%	n
Very easy	4	2
Fairly easy	45	25
Neutral	46	26
Fairly difficult	5	3
Very difficult	0	0

Raters indicated five incident types as particularly difficult (Table 3, showing types indicated by more than 3 raters), and four of these can also be identified as critical based on the number written comments from the reliability test (Table 1): *Administrative processes*, *Clinical processes*, *Healthcare communication and documentation* and *Resources and organization*.

Table 3. Are there incident types that are particularly difficult to understand or use?

	%	n
12. Resources and organization	21	12
1. Administrative processes	18	10
2. Clinical processes	14	8
3. Communication and documentation	11	6
11. Buildings and infrastructure	9	5

Many participants find it difficult to distinguish *1.Administrative processes* from *2.Clinical processes*, in particular if the administrative process concerns a clinical one. And if both types are relevant, it may be difficult to remember indicating all relevant processes. There was confusion with the administrative process *Handovers…*, and its overlap with *3.Communication…*, since handover incidents often involve problems with communication. There were also general problems with distinguishing *3.Communication…* from other incident types, since communication problems can occur in most processes – and several raters requested subtypes for *3.Communication…* Many found it difficult to distinguish between the three first processes in *2.Clinical processes*, in particular between *Screening…* and *Assessment…* Finally, *12.Resources and Organisation* was found to be applicable in most cases, and thus also in need of specification and/or restriction.

Many comments also concerned general issues not related to specific types. Several raters (13 comments) were concerned about using several incident types for a particular case and suggested either a limitation on the number, or a prioritization among the incident types select. There was also discomfort with the lack of distinction between incident and causal factor. A condensation of the comments is presented in Table 4.

6 DISCUSSION

6.1 Failures and causes

Several raters complain that the ICPS-DK has no distinction between failures and causes of failures, as provided in the original ICPS and by most medical error taxonomies [9].

When considering the possible benefits of a separate class for causes one should bear in mind that incident reports often describe one or more chains of multiple failures, where some failures are causes of others, e.g. the wrong setup of an infusion pump (*5.Medical equipment*) resulting in administration of a wrong dose (*4.Medication*). In this case, the distinction between incident type and causal factor is arbitrary and depends on the focus of the particular report or investigation [2], since the same failure may become a background factor in one scenario and a foreground factor in another.

There are two benefits from implementing a separate class for contributing factors as provided by the original ICPS. First, such classification emphasizes the causal relations between different failures in a particular report by focusing on one failure and classifying others as its causes – thus refining the analysis of that report. Second, the *Contributing factors* class also includes further – and significant – elements that "can not be incidents in their own right" [2]: standing conditions [9] or systemic causes, e.g. when the wrong setup of the infusion is due to an inadequate user interface - conditions that may produce several failures and therefore are associated with potential for intervention and learning.

Concerning the first benefit, the advantage of a focused and structural analysis of a particular report is achieved at the cost of its availability for so-called aggregate analysis of several reports describing similar failures, which will be mentioned as incident in one report and as cause in another. In the ICPS, an organizational phenomenon, e.g. a problem with procedures or with team organization can either be categorized as an incident (*Resources/Organizational Management*) or as a contributing factor (*Organizational/Service Factors*) [2]. The choice will largely depend on the focus chosen for the immediate

investigation of the reported incident, and failures classified as causes will not be available for retrieval for analyses with another focus.

Table 4. Problems and suggestions from the comments.

	Problems	*Suggestions*
1. Admin. processes	Overlaps with *Clinical processes*, e.g. when - patient already involved - adm. process concerns a clinical process (e.g. ordering medicine or materials) Difficult to remember all relevant subtypes for a case Overlaps with *Communication…* *Handovers…* - Difficult to distinguish from *Communication* and *Resources*… - Does it only include shift across sectors and institutions? *Continuity gap*: - Also relevant for other incident types, e.g. *Clinical processes* - Overlaps with *Handovers*… - Overlaps with *Communication*	*Documentation* should belong here Prolonged stay at hospital Staff waiting for staff *Admission* should include outpatients
2. Clin. Processes	How to classify surgical incidents? Difficult to distinguish first four subtypes *Screening…* overlaps with *Assesment…* How to classify observation, surveillance? Confusion about *Test*… Expect blood tests to belong to *Blood*… Are X-ray images included in *Test*? No subtype for absconding? - Not covered by 'Detention…'	*Continuity gap* also belongs here *Test*… should be *Administrative process*
3. HC comm. and doc.	Very broad category Does Health care IT belong here? What about technical problems with comm. tech.?	Subtypes, e.g. verbal comm. *Doc*. should be subtype for other incident types *Doc*. should be an 'Administrative process'
12. Res. and org.	Very broad category Difficult to determine as contributing factor	Sharper definition Subtypes, e.g. Protocols etc.
General	Classification based on incidents or causes? Too many types for one incident report: meaningless	Based on systemic models Max. number of types for one case Prioritization of types for one case

On the other hand, if a 'background' failure in one report is also classified as an incident (rather than as a factor), the report can also be retrieved when someone decides to focus an aggregate analysis on that type of

incidents – thus moving it to the 'foreground' of an analysis. Classifying all failures described in a given incident report as incident types will thus make the database more useful for aggregate analysis. This should enable more flexible safety management based approaches to incident analysis used in industrial safety analysis and often represented by the bow-tie model [11;12].

Concerning the second benefit of a separate class for causes, it is worth noticing that the inclusion of standing conditions requires an ambiguous or dualistic definition of *Contributing factors,* as also indicated by WHO: "a circumstance, action or influence" [2]. This duality is particularly evident in the dual representation of organizational phenomena in ICPS, since the corresponding category for contributing factors is intended to cover both 'background' organizational incidents *and* standing conditions. ICPS-DK has omitted a separate class for contributing factors to avoid this duality and simplify classification, although the duality is now represented within some of the *incident types* that also represent standing conditions.

6.2 High prevalence of ambiguous incident types

However, this redefinition – expansion of several incident types to include systemic causes – creates another problem for the use of ICPS: the extensive use of the two types *12.Resources and Organization* and *3.Healthcare Communication and Documentation* as evident in the comments and confirmed as high prevalence in the reliability test [13]. With high prevalence these types become non-informative, and the database will lose its potential, both for statistical purposes and as a vehicle for retrieval of incidents for aggregate analyses. These types are often chosen, both because they represent 'background' incidents that are often involved in other types of incidents with more direct (potential) effect on a patient, and because the characteristics of standing conditions make them difficult to identify directly, relying instead of interpretation sometimes bordering on pure speculation. Risk managers are trained to look for root causes [14], and they may want to compensate for the individual perspective of the original reporter, typically a healthcare professional with limited attention to organizational factors.

6.3 Speculative causes

Some examples will illustrate how raters sometimes go beyond the literal contents of reports and infer problems with, e.g., resources, procedures, staffing – ceding to the temptation described on participant to "classify based on her knowledge of the case or of her organization", and thus going beyond the requirement not classify according to speculation.

For instance, a reporter will focus on specific and individual aspects and may fail to mention organizational factors that seem obvious to the rater. In one of the test incidents the reporter states that he must remind himself to ignore interruptions. However, several raters identify interruptions as an organizational problem – requiring organizational measures to control or reduce them.

Similarly, problems with individual competences (a human or individual factor) may be interpreted as organizational problems with training and introduction (organizational factor). A case of faulty operation of equipment inspires a rater to indicate organizational problems (guidelines, training). A case involving a mistake by a temporary nurse prompts a rater to use *12.Resources and organization* to indicate organizational problems with competences, introduction and guidelines. Another incident which was described as caused by "inadequate understanding of the situation" induces one rater to associate 'inadequate understanding' (a human factor) with 'inadequate training' (an organizational factor).

6.4 Speculation reserved for further analysis

These examples suggest that speculative interpretation of causes is motivated by the prospect of organizational learning by lifting the focus from individual human factors at the sharp end [10] to organizational factors with a potential for improvement, and by a need to compensate for the well known lack of information about systemic causes in incident reports [9] – possibly due to the limited perspective of a reporter less attentive to organizational factors when writing the report.

Although some interpretation beyond the literal content may be necessary, and a total ban against speculation may constitute a barrier to organizational learning, such classification based on insufficient information will generally lead to invalid conclusions and flood the reporting system with pleas for premature organizational changes [15]. We therefore maintain our recommendation that speculations should be avoided, and classification of a single report based on its literal content, while further interpretation and identification of organizational causes may arise, either from focused analysis of individual cases based on additional information, or from aggregate analyses of several similar incidents.

This recommendation, however, may not in reduce the prevalence sufficiently for the type *12.Resources and Organization*, and the addition of mandatory subtypes will elicit more useful information from raters and prompt them to be more specific.

7 CHANGES TO ICPS-DK BASED ON THE COMMENTS

There were two changes of subtypes (processes) under *1.Administrative processes*. First, the generic process *Care flow/patient flow* was introduced, replacing the separate category for *Waiting list...*, making it possible to indicate problems with waiting time and continuity gap – which may be specified if going beyond mandatory reporting to make an *optional* indication of problem: 'Not executed at the right time/postponement'. Second, the subtype *Response to emergency*, included in ICPS but not in the Danish test version, was now added.

In *2.Clinical processes*, two subtypes were modified. *Test*… was changed into *Interpretation of and reaction to examinations and tests*, while examples in the user guide still include problems with delayed or confused specimens. The subtype *Detention/restraint* was changed into *Forced physical or medical treatment* in order to also include forced medication.

The incident type *3.Healthcare communication and documentation* was modified by including four optional subtypes. The rater can thus indicate 1) Type of communication (oral, electronic or paper) 2) 'Between whom', e.g. to indicate whether a healthcare professional has communicated with a patient or another professional, 3) type of document (electronic or paper), and 4) Problem.

Finally, *12.Resources and organization* was changed into *Individual, team and organization* to include a wider and specified range of human and organizational factors, which can be indicated as optional subtypes. With this expansion, this incident type will also capture reports where, e.g., only human factors such as competences are mentioned.

8 LIMITATIONS OF THE STUDY

The raters participating in this study have not been trained in using the ICPS-DK although most had experience from the previous and much simpler reporting system classification.

Some of the raters' comments about lack of details may reflect the fact that they had access to only the mandatory incident types (Table 1) and their definitions.

Due to the focus of the study and the questionnaire design, comments are mainly directed at problems with the classification rather than positive aspects of usability. Nevertheless, a few participants did comment on ICPS-DK being easier to use than the first version of the Danish reporting system.

The case-mix used was selected to cover all the incident types and subtypes, and a random sample of cases might be thought to possibly have challenged the completeness of ICPS-DK by revealing a greater need for new and additional incident types. Yet this does not seem very likely as each case was assigned to several more incident types than the one type the case was selected to cover. Hence, the casemix is not restricted to the selection criteria.

9 CONCLUSION

Half of the respondents found ICPS-DK fairly easy to use and only 5% found it difficult. This is promising, because ICPS-DK is much more comprehensive than the classification used in the previous reporting system, and moreover, a third of the respondents had no prior experience with classifying events, and none were familiar with this new classification.

The incident types and subtypes of the mandatory version of ICPS-DK were found to be exhaustive for the classification of the broad case-mix used.

However, the usability revealed some challenges with some elements of the basic ICPS framework, as well as challenges with the Danish adaptation. There is some confusion over the use of non-exclusive categories – a challenge inherent in the ICPS, although further aggravated with the lack of a separate class for contributing factors in the Danish adaptation. There is also some confusion over: the distinction between clinical and administrative processes, especially for processes directly involving a patient; the classification of handovers and continuity gaps; the distinction between the first clinical processes (subtypes); the separate classification of documentation incidents since these are regarded as belonging to a specific process; classification of IT problems; classification of surgical incidents; classification of incidents involving test results, especially lab tests.

Some of the main challenges related to the Danish adaptation concern the lack of a class for contributing factors, which instead are represented by allowing the use of several types and by expanding the definition of two incident types to include latent conditions.

The usability study reveals one inconvenience of this approach: The two incident types that are also used to indicate latent conditions – *12.Resources and Organization* and *3.Communication and Documentation* – may be used for a large proportion of cases, especially if raters are keen to look for systemic causes. In this case, when categorization into these types makes them highly prevalent, as documented in a parallel paper [7], they become non-informative. Furthermore, *3. Communication and Documentation* generally overlaps with several other incident types, since many incidents somehow involve communication problems.

The most promising and efficient way of reducing this problem seems to be for raters to follow a recommendation to be specific and thus use subtypes and to avoid speculation beyond what is written in the report.

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